REMARKS

The outstanding Official Action imposes a restriction requirement arguing that the 41 claims currently in this application encompass three independent and distinct inventions.

The first alleged independent and distinct invention is denoted as Group I, encompassing Claims 18 to 28, drawn to a method of treating inflammatory conditions which comprises administering, to a mammal in need thereof, an effective amount of a cyclic compound whose complete definition is set forth in independent Claim 18.

The second invention, stated as Group II, includes Claims 29 to 43, directed to a method of treating tissue repair conditions comprising administering, to a mammal in need thereof, an effective amount of a cyclic compound whose definition is set forth in independent Claim 29. The cyclic compounds of Group II are identical to the cyclic compounds of Group I.

The third invention, set forth as Group III, comprises Claims 44 to 58. Claims 44 to 58 are drawn to a method of treating infectious conditions comprising administering, to a mammal in need thereof, an effective amount of a class of cyclic compounds defined in independent Claim 44. This class of cyclic compounds is identical to the class of compounds within the scope of Groups I and II. It is noted that the Official Action, due to a typographical error, recites that Group III is drawn to the method of treating tissue repair conditions.

The Official Action argues that the inventions of Groups I, II and III are unrelated because they are not capable of use together and have different modes of operation, different functions and different effects, citing MPEP §§806.04 and 808.01.

Applicant respectfully traverses the imposition of this restriction requirement. The grounds imposed in the Official Action, e.g. that the invention of Groups I, II and III are

unrelated, is not a statutory grounds for imposition of a restriction requirement. To impose a restriction requirement the claims of an application must be directed to independent and distinct inventions. 35 U.S.C. §121. The Official Action has not so much as alleged that the three sets of claims represent separate distinct and independent inventions.

Indeed, definitions for distinctiveness between sets of claims are set forth in the Manual of Patent Examining Procedure (MPEP) at §806.05(c) to §806.05(i). In support of restriction, however, the Official Action advances MPEP §§806.04 and 808.01. These sections of the MPEP refer to species and independent inventions, respectively. These sections of the MPEP provide no guidance regarding distinctiveness.

These sections of the MPEP are emphasized insofar as the grounds imposed for restriction in the outstanding Official Action are improper. The Official Action states that the invention defined by the claims of the present application are subject to restriction because the claims employ different modes of operation, different functions or different effects. It is emphasize that even the MPEP admits that such grounds for restriction, except for species, are rarely presented. MPEP §808.01.

So it is in the present application. The three sets of claims are not directed to distinct species. Indeed, the compounds within the contemplation of each of the alleged separate and distinct inventions are identical. It is important to appreciate that the requirement for restriction is proper only if different modes of operation, different functions or different effects are not presented. (Emphasis added). That is, if the claims subject to restriction includes one of the three effects then a restriction requirement is improper.

All the claims of the present application are directed to a method of treating inflammatory conditions, tissue repair conditions or infectious conditions utilizing the same

class of cyclic compounds. The specification teaches that this class of cyclic compounds provides growth factor modulating activity. Since each of the conditions treated are based on growth factor activity, all the claims of the present application are directed to the same effect As such, the sections of the MPEP support, rather than rebut, the unity of invention of all the claims of the present application.

The above remarks establish that all the claims of the present application are independent and distinct as those terms are set forth in the statute, 35 U.S.C. §121, and as that statute is interpreted by the MPEP.

It is useful to analyze the first sentence of 35 U.S.C. §121 which is as follows:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions. (Emphasis added)

Pursuant to this statutory dictate, the implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct. 37 C.F.R. §§1.141 - 1.142. Without both independence and distinctiveness, a restriction requirement is not authorized.

In the present application the three sets of claims, which the Official Action has grouped as separate inventions, are not independent of each other so as to justify a restriction requirement. The claims of Group I, e.g. Claims 18-28, Group II, e.g. Claims 29-43, and Group III, e.g. Claims 44-58, are each drawn to a method of treatment. These claims cannot be considered "independent" of the claims of each other since they all depend upon the common growth factor modulating activity of the same class of cyclic compounds. Therefore, rather than being independent of each other, the claims of the present application are interrelated and interdependent.

The interdependence of the three allegedly independent sets of claims, set forth in the Official Action, is confirmed -- indeed it is mandated -- by virtue of the fact that the descriptive requirements of 35 C.F.R. §112 compel disclosure of all aspects of the three allegedly distinct and independent inventions of the present application. An application claiming a method of treatment of growth factor activity must, of necessity, describe all such activity treated. That activity is defined by all the method claims of the present application, Claims 18-58. Consequently, it is clear that all aspects of the present invention, including the method of Groups I, II and III, are necessarily interdependent, not independent of each other. Thus, the above remarks provide yet further support for the proposition that the requirement for restriction in the present application is misplaced.

Applicants note that the instant restriction requirement is supported by reference to different classes and subclasses of the Patent and Trademark Office classification system in which the three groups of claims are classified. The inference that the classification of claims support a restriction requirement is submitted to be improper.

Reliance on a supposed classification of groups of claims does not establish independence and distinctiveness. The classification system has no statutory recognition with regard to whether inventions are independent and distinct. The sole purpose of the classification system is as an aid in identifying and searching for patents directed to the same general inventive entity.

The classification system is also an unreliable basis for requiring restriction between claims to various aspects of applicant's unitary invention because the Patent and Trademark Office classification system exhibits considerable overlap of technical definitions. In

particular, the definition of classes and subclasses in the classification system does not prevent rejection of claims found in patent references classified in other classes or subclasses.

Furthermore, the classification system is a poor basis for restriction between related aspects of an invention insofar as classification definitions change over time. Thus, a classification that may have seemed to support restriction at a given time can change, thereby casting a shadow over the propriety of a restriction requirement later during the term of patents issued from parent and divisional applications. Indeed, classifications change in response to consideration of administrative convenience, often in response to nothing more than growth in the number of patents in a given class or subclass. These considerations have nothing to do with whether the subject matter of patents assigned to different classifications are "independent and distinct," as those terms are used in 35 C.F.R.§121, which fact proves that basing restriction requirements on the classification system is improper.

It is emphasized that the restriction requirement of record is not mandatory and is indeed contrary to the public interest. Courts have recognized that it is in the public interest to permit an applicant to claim all aspects of an invention in a single application, as applicants have done herein. The CCPA has observed:

> We believe that the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe, in a manner required by 35 U.S.C. §112, all aspects as to what they regard as their invention, regardless of the number of statutory classes involved. In re Kuehl, 456 F.2d 658, 666, 117 USPQ 250, 256 (CCPA 1973).

This interest is consistent with the practical reality that a sufficiently detailed description supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application directed to other aspects of the invention.

Applicant respectfully suggests that in view of the continued increase in official fees and the resultant potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose of promoting and encouraging the progress of science and the useful arts.

It is vital that restriction requirements issue with only the proper statutory authorization because patents issuing on divisional applications, which are filed to prosecute claims that are held to be distinct and independent, can be vulnerable to legal challenge predicated upon the allegation of double patenting.

The third sentence of 35 U.S.C. §121, which states that a patent issuing on a patent application "shall not be used as a reference" against the divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that §121 protects a patentee from an allegation of same invention double patenting. Studiengellschaft Kohle mvP v. Northern Petrochemical Co., 784 F.2d 351, 355, 228 USPQ 837, 840 (Fed. Cir. 1986).

The same Court in Gerber Garment Technologies Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 USPQ2d 1436 (Fed. Cir. 1990) held that § 121 does not insulate a patentee from an allegation of "obviousness-type" double patenting and, in fact, the invalidation, on double patenting grounds, of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a Terminal Disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on a divisional application.

Although applicant has met the requirement that he elect the claims of one of the alleged inventions for prosecution on the merits, i.e. Group I, encompassing Claims 18-28, applicant submits that the above remarks establish the unitary nature of the claims of the present application which have been made subject to restriction. Reconsideration and removal of the provisional restriction requirement of record is thus deemed appropriate. Such action is respectfully urged.

The Official Action also imposes a species election. Applicant has elected, with traverse, as a single disclosed species, the compound 1,2-O-ethylene-ß-D-fructopyranoside-2,3,4-trisphosphate. Applicant avers that Claims 18 to 22 and 24 to 28 of elected Group I reads on this elected species.

This election of the compound 1,2-O-ethylene-ß-D-fructopyranoside-2,3,4-trisphosphate, mentioned in the specification at Page 6, on the penultimate and ultimate lines, applicant avers, is inappropriate. The number of cyclic compounds within the scope of the present invention is not so voluminous as to present a burdensome search. Indeed, the class of compounds within the scope of the present invention is set forth in great detail so that a search of the art may be easily conducted. To penalize applicant, by requiring the filing of three separate applications, is deemed inappropriate given the non-burdensome nature of this search required. Reconsideration and removal of this species election requirement is therefore deemed appropriate. Such action is respectfully urged.

The above remarks emphasize the improper nature of the restriction requirement and species election of record. Reconsideration and removal of these requirements, followed by prompt examination on the merits of all the claims currently in this application, Claims 18-58,

is therefore respectfully solicited.

Respectfully submitted,

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